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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,134	12/20/2001	Parris S. Wellman	102863-0017	4419

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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,134

Applicant(s)

WELLMAN ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

2nd Supplemental Office Action

This is a supplemental Final Rejection. The previous office action, a final rejection objected to claims 6, 11 and 16. New art has been used to reject these claims. Presently, all claims are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-13, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is unclear as to what Applicant means by “a non-destructive tissue-contacting conductive surface” in claim 1, lines 2-3 and claim 13, lines 3-4. There is no reference in the specification as to “a non-destructive tissue-contacting conductive surface.” Therefore this phrase is considered New Matter.

For the purposes of examination the examiner will assume that “a non-destructive tissue-contacting conductive surface” is a surface used for tissue grasping not tissue cutting and will apply the art appropriately.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 8, 10, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1).

Regarding claims 1, 2, 7 and 13, Yamanashi et al. disclose a bipolar forceps device having a sharp pointed tissue-piercing distal tip, first and second members having non-

destructive tissue-contacting conductive surfaces (tissue grasping surfaces of the jaw members (40 and 38)), wherein the first and second members are pivotably movable with respect to each other and connected to a power source, see col. 2-5 and figures 2, 3 and especially 4. Yamanashi et al. fail to explicitly show the pivot connected the first and second members and do not show a close up of the first and second conductive elements connected to the first and second members respectively. It is well known in the art to provide the first and second members disclosed by Yamanashi et al. with a pivotable connection in order to facilitate the opening and closing of the members with respect to each other and to place a first electrically conductive element on the first member and a second electrically conductive element on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces. As an illustrative example, Dorn discloses an electrosurgical forceps device and teach providing a pivot pin (72) between the first (16) and second (14) members in order to provide the members with opening and closing capabilities with respect to each other and also teach placing a first electrically conductive element (38) on the first member and a second electrically conductive element (36) on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces, see col. 4-7 and figures 1-3. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al., as is well known in the art and taught by Dorn, to provide a pivot pin between the first and second members in order to provide the members with opening and closing capabilities with respect to each other and also teach placing a first electrically conductive element on the

first member and a second electrically conductive element on the second member in order to provide the bipolar electrosurgical forceps with grasping coagulating tissue grasping surfaces.

Regarding claims 3 and 15, Yamanashi et al. in view of Dorn disclose an actuating member (loop rings of handle) mated to the first and second members and effective to selectively move the members between the open and closed positions, see figure 4 of Yamanashi et al..

Regarding claim 4, Yamanashi et al. in view of Dorn further that first and second members are elongate and each member includes a proximal end mated to the actuating member, and a distal portion having the conductive element disposed thereon.

Regarding claim 8, Yamanashi et al. in view of Dorn further that one of the first and second conductive elements is an active energy transmitting electrode, and the other one of the first and second conductive elements is a return electrode (this is inherent in a bipolar device).

Regarding claim 10, Yamanashi et al. in view of Dorn further disclose that an insulative coating (34 and 32) disposed around a portion of at least one of the first and second members, see Dorn figure 2 and col. 5.

Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) as applied to claim 1 above, and further in view of Nezhat et al. (USPN 6,514,252 B2).

Regarding claim 6, Yamanashi et al. in view of Dorn disclose the claimed invention except for explicitly reciting that the first conductive element comprises first and second electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member. Nezhat et al. disclose a bipolar forceps instrument and teach the use of a large number of alternate electrically conductive jaw surface configuration including one wherein the first conductive element (108) comprises first (100a) and second (100b) electrodes extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode (102) extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member, see col. 2-5, col. 10, lines 1-36 and figure 9D. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Nezhat et al., to provide an alternate jaw surface configuration wherein the first conductive element comprises first and second electrodes

extending along the length of the distal portion of the first member and adapted to be positioned adjacent a tissue surface, and the second conductive element comprises a single electrode extending along the length of the distal portion of the second member and adapted to be positioned adjacent an opposed tissue surface between the first and second electrodes of the first member.

Regarding claim 16, Yamanashi et al. in view of Dorn in further view of Nezhat et al. disclose the claimed invention, see Nezhat et al. figure 9D.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) as applied to claim 1 above, and further in view of Swanson et al. (USPN 6,610,055 B1).

Regarding claim 9, Yamanashi et al. in view of Dorn disclose the claimed invention except for explicitly reciting that at least one of the first and second members is malleable. Swanson et al. disclose an electrosurgical forceps device and teach that "the forceps-like apparatus 150 includes arms 154 and 156 that are pivotably secured to one another by a pin 158 to allow the device to be opened and closed. The proximal portions of the arms 154 and 156 may be formed from rigid or malleable material. The arm distal portions 160 and 162, which are curved and support the tissue coagulation apparatus 152, are preferably formed from malleable material. This allows the arm distal portions 160 and 162 to be re-shaped by the physician as needed for particular procedures and body

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structures (note the dash lines in FIG. 21), see col. 16, line 63 through col. 17, line 10 and figures 21-25. Arms 154 and 156 are analogous to the first and second members.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Swanson et al., to provide the first and second members in a malleable form in order to be re-shaped by the physician as needed for particular procedures and body structures.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamanashi et al. (USPN 5,964,759) in view of Dorn (USPN 6,334,860 B1) as applied to claim 1 above, and further in view of Chen et al. (USPN 6,102,909).

Regarding claim 12, Yamanashi et al. in view of Dorn disclose the claimed invention except for explicitly reciting that the first and second members are biased in the closed position. It is well known in the art to bias the jaw members of forceps in order to hold tissue. Chen et al. disclose an electrosurgical instrument and teach providing the instrument with a means to bias the opposing members in an open or closed position depending on the desired effect, see col. 5, lines 3-6 and col. 16, lines 30-39. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yamanashi et al. in view of Dorn, as taught by Chen et al., to provide the instrument with a means to bias the opposing members in an open or closed position depending on the desired effect.

Claims 1, 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fozard (USPN 2,888,927) in view of Mehl, Sr. (USPN 5,846,252)

Regarding claim 1, Fozard discloses a medical device (11) comprising a first member (distal portion of first 24 ending in 19) having a first non-destructive tissue-contacting conductive element in communication with a source (10) of ablative energy; and a second member (distal portion of second 24 ending in 18) having a second non-destructive tissue-contacting element, the second member being pivotally coupled (22) to the first member and including a distal tissue-piercing tip adapted to be deployed into tissue to allow the first conductive element to be positioned on a first tissue surface and the second conductive element to be positioned on a second tissue surface opposed to the first tissue surface such that ablative energy can be transmitted between the first and second conductive elements, see col. 1-2 and figure 1. Fozard fails to disclose a second electrically conductive element on the second member because Fozard discloses a monopolar device. It is extremely well known in the art to bipolar capability to monopolar devices in order to obtain higher localized current densities. Mehl, Sr. discloses a medical device similar to that of Fozard (both are electrical tweezer/forceps devices directed to the removal of hair) and teach the use of a first electrically conductive element (24) disposed on the first member (20) and a second electrically conductive element (26) disposed on the first member (22) in order to provide a bipolar configuration, see col. 3 and figures 1 and 2. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of

Fozard, as is well known in the art and taught by Mehl, Sr., to use a first electrically conductive element disposed on the first member and a second electrically conductive element disposed on the second member in order to provide a bipolar configuration.

Regarding claim 3, Fozard further discloses an actuating member (proximal portions of both 24's) mated to the first and second members and effective to selectively move the members between the open and closed positions, see col. 1-2 and figure 1.

Regarding claim 11, Fozard further discloses that the actuating member comprises opposed first and second handles (proximal portions of both 24's), wherein a force applied to bring the first and second handles in contact with each other causes opening of the first and second members, see col. 1-2 and figure 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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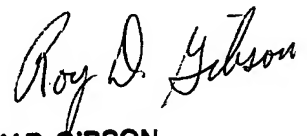
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. A.R.
September 15, 2004


ROY D. GIBSON
PRIMARY EXAMINER